



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA-HQ-OPPT-2011-0941; FRL-6369-9]

RIN 2070-AB27

Proposed Significant New Use Rule on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for four chemical substances which were the subject of premanufacture notices (PMNs). This action would require persons who intend to manufacture, import, or process any of the chemical substances for an activity that is designated as a significant new use by this proposed rule to notify EPA at least 90 days before commencing that activity. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit the activity before it occurs.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2011-0941, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail*: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. ATTN: Docket ID Number EPA-HQ-OPPT-2011-0941. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2011-0941. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or email. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through regulations.gov, your email address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your

comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:*

Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, import, process, or use the chemical substances contained in this proposed rule. The following list of North American Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers, importers, or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemical substances subject to a final SNUR must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of a proposed or final

SNUR, are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A. What Action is the Agency Taking?

EPA is proposing these SNURs under TSCA section 5(a)(2) for four chemical substances which were the subject of PMNs P-07-204, P-10-58, P-10-59, and P-10-60. These SNURs would require persons who intend to manufacture, import, or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

In the **Federal Register** issue of September 21, 2012 (77 FR 58666) (FRL-9357-2), EPA issued direct final SNURs on these four chemical substances in accordance with the procedures at § 721.160(c)(3)(i). EPA received notice of intent to submit adverse comments on these SNURs. Therefore, as required by § 721.160(c)(3)(ii), EPA has removed the direct final SNURs in a separate final rule published in the **Federal Register**, and is now issuing this proposed rule on the four chemical substances. The record for the direct final SNURs on these chemical substances was established as docket EPA-HQ-OPPT-2011-0941. That docket includes information considered by the Agency in developing the direct final rule and the notice of intent to submit adverse comments.

B. What is the Agency's Authority for Taking this Action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the chemical substance for that use. Persons who must report are described in § 721.5.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. According to § 721.1(c), persons subject to these SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorized EPA to consider any other relevant factors.

To determine what would constitute a significant new use for the four chemical substances that are the subject of this proposed rule, EPA considered relevant information about the toxicity of the chemical substances, likely human exposures and environmental releases associated with possible uses, and the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to this Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for four chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.

- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the TSCA section 5(e) consent order or, for TSCA non-section 5(e) SNURs, the basis for the SNUR (i.e., SNURs without TSCA section 5(e) consent orders).
- Tests recommended by EPA to provide sufficient information to evaluate the chemical substance (see Unit VIII. for more information).
- CFR citation assigned in the regulatory text section of this proposed rule.

The regulatory text section of this proposed rule specifies the activities designated as significant new uses. Certain new uses, including production volume limits (i.e., limits on manufacture and importation volume) and other uses designated in this proposed rule, may be claimed as CBI. See Unit IX.

This proposed rule includes PMN substances P-10-58, P-10-59, and P-10-50 that are subject to “risk-based” consent orders under TSCA section 5(e)(1)(A)(ii)(I) where EPA determined that activities associated with the PMN substances may present unreasonable risk to human health or the environment. These consent orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The so-called “TSCA section 5(e) SNURs” on these PMN substances are proposed pursuant to § 721.160, and are based on and consistent with the provisions in the underlying consent orders. The TSCA section 5(e) SNURs designate as a “significant new use” the absence of the protective measures required in the corresponding consent orders.

This proposed rule also includes a SNUR on PMN substance P-07-204 that was not subject to a consent order under TSCA section 5(e). In this case, EPA did not find that the use scenario described in the PMN triggered the determinations set forth under TSCA section 5(e). However, EPA does believe that certain changes from the use scenario described in the PMN could result in increased exposures, thereby constituting a “significant new use.” This so-called “TSCA non-section 5(e) SNUR” is proposed pursuant to § 721.170. EPA has determined that every activity designated as a “significant new use” in all TSCA non-section 5(e) SNURs issued under § 721.170 satisfies the two requirements stipulated in § 721.170(c)(2), i.e., these significant new use activities, “(i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice, and (ii) may be accompanied by changes in exposure or release levels that are significant in relation to the health or environmental concerns identified” for the PMN substance.

PMN Number P-07-204

Chemical name: Pentane, 1,1,1,2,3,3- hexafluoro-4-(1,1,2,3,3,3-hexafluoropropoxy)-.

CAS number: 870778-34-0.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a heat transfer fluid. Based on test data on the PMN substance and structure activity relationship (SAR) analysis of test data on analogous perfluorinated substances, EPA identified concerns for neurotoxicity and liver effects from exposures to the PMN substance. For the uses described in the amended PMN, EPA does not expect significant

worker exposures due to the use of impervious gloves. Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk. EPA has determined, however, that any use of the substance without impervious gloves, where there is a potential for dermal exposure; or any use of the substance other than as described in the amended PMN may cause serious health effects. Based on this information, the PMN substance meets the concern criteria at § 721.170 (b)(3)(i) and (ii).

Recommended testing: EPA has determined that the results of a 28-day dermal toxicity test (OPPTS Test Guideline 870.3200) in rats, a 90-day inhalation toxicity test (OPPTS Test Guideline 870.3465), and a test using the “Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact” (American Society for Testing and Materials (ASTM) International Standard F739-12) as reported in the “Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing” (ASTM International Standard F1194-99 (2010)) would help characterize the human health effects of the PMN substance.

CFR citation: 40 CFR 721.10509.

PMN Numbers P-10-58, P-10-59, and P-10-60

Chemical names: Partially fluorinated alcohol substituted glycols (generic).

CAS numbers: Not available.

Effective date of TSCA section 5(e) consent order: October 8, 2010.

Basis for TSCA section 5(e) consent order: The PMN states that the generic (non-confidential) uses of the PMN substances will be as intermediates (P-10-58 and P-10-59)

and a surface active agent (P-10-60). EPA has concerns for potential incineration or other decomposition products of the PMN substances. These perfluorinated decomposition products may be released to the environment from incomplete incineration of the PMN substances at low temperatures. EPA has preliminary evidence, including data on some fluorinated polymers, which suggests that, under some conditions, the PMN substances could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic to people, wild mammals, and birds. These concerns are based on data on analogous chemical substances, including perfluorooctanoic acid (PFOA) and other perfluorinated alkyls, including the presumed environmental degradant. The order was issued under TSCA sections 5(e)(1)(A)(i), 5(e)(1)(A)(ii)(I), and 5(e)(1)(A)(ii)(II), based on a finding that these substances may present an unreasonable risk of injury to the environment and human health, the substances may be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substances and their potential degradation products. To protect against these exposures and risks, the consent order requires submission of testing on the PMN substance P-10-60 at five identified aggregate manufacture and importation volumes; requires analysis of raw materials; and restricts the use of P-10-58 and P-10-59 as intermediates to make P-10-60. The SNUR designates as a “significant new use” the absence of these protective measures.

Recommended testing: EPA has determined that the results of certain fate and physical/chemical property testing identified in the TSCA section 5(e) consent order would help characterize possible effects of the PMN substances and their degradation

products. The TSCA section 5(e) consent order contains five production volume limits. The PMN submitter has agreed not to exceed the confidential production volume limits without performing the specified testing on PMN substance P-10-60. Additional testing is included in the preamble to the TSCA section 5(e) consent order, but this testing is not required at any specified time or production volume. However, the TSCA section 5(e) consent order's restrictions on manufacture, import, processing, distribution in commerce, use, and disposal of the PMN substance will remain in effect until the TSCA section 5(e) consent order is modified or revoked by EPA based on submission of that or other relevant information.

CFR citation: 40 CFR 721.10515.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the four chemical substances that are subject to these proposed SNURs, EPA concluded that for three of the substances, regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health and environmental effects of the chemical substances. For one of the four substances, where the uses are not regulated under a TSCA section 5(e) consent order, EPA determined that one or more of the criteria of concern established at § 721.170 were met. The basis for these findings is outlined in Unit IV.

Based upon comments received from the September 21, 2012 direct final rule, the proposed SNUR for P-10-58, P-10-59, and P-10-60 has been amended to be consistent with the provisions of the TSCA section 5(e) consent order and the proposed SNUR for

P-07-0204 has been amended to clarify the restriction at 721.80(j). This proposed rule includes the following changes:

1. Revision of paragraph (a)(2)(i) for the proposed SNUR on P-10-58, P-10-69, and P-10-60.
2. Revision of paragraph (a)(2)(ii) for the proposed SNUR for P-07-0204.

B. Objectives

EPA is proposing these SNURs for specific chemical substances that have undergone premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses designated in this proposed rule:

- EPA would receive notice of any person's intent to manufacture, import, or process a listed chemical substance for the described significant new use before that activity begins.
- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for the described significant new use.
- EPA would be able to regulate prospective manufacturers, importers, or processors of a listed chemical substance before the described significant new use of that chemical substance occurs, provided that regulation is warranted pursuant to TSCA sections 5(e), 5(f), 6, or 7.
- EPA would ensure that all manufacturers, importers, and processors of the same chemical substance that is subject to a TSCA section 5(e) consent order are subject to similar requirements.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory).

Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at

<http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VI. Applicability of the Proposed Rule to Uses Occurring Before Effective Date of the Final Rule

To establish a significant “new” use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. TSCA section 5(e) consent orders have been issued for three chemical substances and the PMN submitters are prohibited by the TSCA section 5(e) consent orders from undertaking activities which EPA is designating as significant new uses. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no other person may commence such activities without first submitting a PMN. For chemical substances for which an NOC has not been submitted at this time, EPA concludes that the uses are not ongoing. However, EPA recognizes that prior to the effective date of the final rule, when chemical substances identified in these SNURs are added to the TSCA Inventory, other persons may engage in a significant new use as defined in this proposed rule before the effective date of the final rule.

As discussed in the SNURs published in the **Federal Register** issue of April 24, 1990 (55 FR 17376), EPA has decided that the intent of TSCA section 5(a)(1)(B) is best

served by designating a use as a significant new use as of the date of publication of the September 21, 2012 direct final rule rather than as of the effective date of the final rule for this proposed rule. If uses begun after publication were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notification requirements because a person could defeat the SNUR by initiating the significant new use before the proposed rule became an effective final rule, and then argue that the use was ongoing before the effective date of the final rule based on this proposed rule. Thus, persons who begin commercial manufacture, import, or processing of the chemical substances regulated through these SNURs will have to cease any such activity before the effective date of the final rule based upon this proposed rule. To resume their activities, these persons would have to comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions expires.

EPA has promulgated provisions to allow persons to comply with these SNURs before the effective date of the final rule. If a person meets the conditions of advance compliance under § 721.45(h), the person is considered exempt from the requirements of the SNUR.

VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not require developing any particular test data before submission of a SNUN. The two exceptions are:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. In cases where EPA issued a TSCA section 5(e) consent order that requires or recommends certain testing, Unit IV. lists those tests. Unit IV. also lists recommended testing for TSCA non-section 5(e) SNURs. Descriptions of tests are provided for informational purposes. EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select “Test Methods and Guidelines.” ASTM International standards are available at <http://www.astm.org/Standard/index.shtml>.

In the TSCA section 5(e) consent orders for three of the chemical substances in this proposed rule, EPA has established production volume limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of toxicity tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. Under recent TSCA section 5(e) consent orders, each PMN submitter is required to submit each study before reaching the specified production limit. The SNURs contain the same production volume limits as the TSCA section 5(e) consent order. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the

production limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture, import, or processing.

The recommended tests specified in Unit IV. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth

in 40 CFR 720.40 and § 721.25. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers, importers, and processors of the chemical substances during the development of the direct final rule. EPA's complete economic analysis is available in the docket under docket ID number EPA-HQ-OPPT-2011-0941.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

This proposed rule would establish SNURs for four chemical substances that were the subject of PMNs, and in three cases, a TSCA section 5(e) consent order. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993).

B. Paperwork Reduction Act (PRA)

According to the PRA (44 U.S.C. 3501 *et seq.*), an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR

No. 574). This action would not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

On February 18, 2012, EPA certified pursuant to RFA section 605(b) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
2. The SNUR submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this proposed rule.

This proposed rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit IX. and EPA's experience

promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.
- Submission of the SNUN would not cost any small entity significantly more than \$8,300.

Therefore, the promulgation of these SNURs would not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government would be impacted by this proposed rule. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

E. Executive Order 13132

This action would not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999).

F. Executive Order 13175

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

G. Executive Order 13045

This action is not subject to Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211

This proposed rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action would not involve any technical standards, NTTAA section 12(d) (15 U.S.C. 272 note), would not apply to this action.

J. Executive Order 12898

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: January 14, 2013.

Maria J. Doa,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 721--[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. Add § 721.10509 to subpart E to read as follows:

§ 721.10509 Pentane, 1,1,1,2,3,3- hexafluoro-4-(1,1,2,3,3,3- hexafluoropropoxy)-.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as pentane, 1,1,1,2,3,3- hexafluoro-4-(1,1,2,3,3,3- hexafluoropropoxy)- (PMN P-07-204; CAS No. 870778-34-0) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (a)(2)(i), (a)(3), (b) (concentration set at 1.0%), and (c).

(ii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j) (applies specifically to the confidential uses identified in the amended premanufacture notice (PMN)).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph. (1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), (d), (e), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(ii) of this section.

3. Add § 721.10515 to subpart E to read as follows:

§ 721.10515 Partially fluorinated alcohol substituted glycols (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substances identified generically as partially fluorinated alcohol substituted glycols (PMN P-10-58, P-10-59, and P-10-60) are subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k) (manufacture and import of the PMN substances according to the chemical synthesis and composition section of the TSCA section 5(e) consent order, including analysis, reporting, and limitations of maximum impurity levels of certain fluorinated impurities; manufacture and import of P-10-58 and P-10-59 only as intermediates for the manufacture of P-10-60), and (q).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph.

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (i) are applicable to manufacturers, importers, and processors of these substances, except the recordkeeping requirements for § 721.125(b) and (c) do not apply to importers or processors when any one of the substances are contained in a formulation at less than 3 weight percent.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

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